

Remarks

Claims 1-2, 4-5, 7-18, 20-31 and 43-44 are pending in this application.

Claims 3, 6 and 19 are canceled without prejudice to Applicant's right to pursue the subject matter recited by them in one or more divisional, continuation and continuation-in-part applications. All of the pending claims are properly supported by the specification and claims as filed. No new matter has been introduced.

A. The Rejection Under 35 U.S.C. § 103 Should Be Withdrawn

The rejection of claims 1, 2, 4, 5, 7-10, 12-18, 20-23 and 44 as allegedly obvious over U.S. Patent No. 5,635,517 to Muller *et al.* ("Muller") is maintained in the Advisory Action. Applicant respectfully traverses this rejection.

As discussed in Applicant's previous responses (which are incorporated herein), Muller does not teach or suggest all of the limitations recited by the pending claims. Muller also would not have provided one of ordinary skill in the art with any expectation of successfully achieving the claimed invention. The Examiner disagrees, asserting that "congestive heart failure is related to the group of ischemic heart diseases that also include [sic] atherosclerosis and coronary heart disease." The Advisory Action of August 12, 2003, page 2; The Final Office Action of May 21, 2003, page 6. However, this assertion does not appear to be based on any medical literature or factual findings.² Moreover, Applicant respectfully submits that this assertion is not correct.

Congestive heart failure, atherosclerosis and restenosis are each distinct diseases with distinct etiologies, and are each treated with different therapies. This is well known in the art as evidenced by the Declaration under 37 C.F.R. § 1.132 of Dr. Donald Baim, submitted herewith. Dr. Baim is a member of the Harvard Medical School faculty and a senior interventional cardiologist and director of the Center for Integration of Medicine and Innovative Technology at the Brigham and Women's hospital. He has been active in research and practice in the field of cardiology for over 30 years.

Dr. Baim explains that atherosclerosis, restenosis and congestive heart failure are three different diseases with different etiologies and treatments. Declaration of Dr. Donald Baim, paragraph 6. Consequently, the fact that a compound can be used to treat

² Because this assertion is apparently based on the Examiner's personal knowledge, Applicant again respectfully requests that the Examiner support this assertion by an affidavit or a declaration. Manual of Patent Examining Procedure, § 2144.03. Without such an affidavit or a declaration, Applicant respectfully submits that the rejection under 35 U.S.C. § 103(a) lacks a legally sufficient basis.

congestive heart failure does not mean that the compound can be used to treat atherosclerosis or restenosis, or vice versa. *Id.* at paragraph 14. Therefore, Dr. Baim concludes that, prior to December 11, 2000, he himself, and others of ordinary skill in the art, would not have thought that the compounds disclosed in Muller are necessarily effective for the treatment or prevention of atherosclerosis or restenosis. *Id.* at paragraph 15.

In sum, the rejection of the claims should be withdrawn for reasons discussed herein and in previous responses. In general, Applicant respectfully submits that a *prima facie* case of obviousness has not been established. This is evidenced, in part, by the declaration submitted herewith. Consequently, Applicant requests that the rejection of the claims under 35 U.S.C. § 103(a) be withdrawn.

Conclusion

For the foregoing reasons, Applicant respectfully submits that claims pending in this application are allowable, and request that the rejections thereof be withdrawn.

No fee is believed due for the submission of this paper. If any fees be required, however, please charge such fees, and any other required fees, to Pennie & Edmonds LLP Deposit Account No. 16-1150.

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Respectfully submitted,



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